EUROPEAN
COMMISSION

Brussels, 15.9.2020
C(2020) 6398 (final)

# COMMISSION IMPLEMENTING DECISION

**of 15.9.2020**

**on the annual renewal of the conditional marketing authorisation for the medicinal product for human use "Ervebo - Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)", granted by Decision C(2019)8131(final)**

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) and 14-a thereof,

Having regard to Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council[2],

Having regard to the application submitted by Merck Sharp & Dohme B.V., on 6 May 2020, under Article 6(2) of Regulation (EC) No 507/2006 with a view to the annual renewal of the conditional marketing authorisation for the medicinal product "Ervebo - Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)",

Having regard to the opinion of the European Medicines Agency, formulated on 23 July 2020 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "Ervebo - Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)", entered in the Union Register of Medicinal Products under the number EU/1/19/1392 and authorised by Commission Decision C(2019)8131(final) of 11 November 2019, remains in compliance with the requirements of Article 14-a of Regulation (EC) No 726/2004 of the European Parliament and of the Council, and Regulation (EC) No 507/2006,

(2) The conditional marketing authorisation should therefore be renewed.

(3) Decision C(2019)8131(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 92, 30.3.2006, p. 6.

(4) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2019)8131(final) should therefore be replaced.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

*Article 1*

The conditional marketing authorisation granted by Decision C(2019)8131(final) of 11 November 2019 is renewed.

*Article 2*

Decision C(2019)8131(final) is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

*Article 3*

The period of validity of the renewed authorisation shall be one year from 13 November 2020.

*Article 4*

This Decision is addressed to Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, Nederland.

Done at Brussels, 15.9.2020

*For the Commission*

*Anne BUCHER*
*Director-General*